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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,423	09/27/2001	Amos Nussinovitch	919 1002	7772

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EXAMINER	
NAFF, DAVID M	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,423	NUSSINOVITCH ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/12/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13,14,21,22,25-41 and 44-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13,14,21,22,25-41 and 44-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 10/12/04 amended the title, the specification, and claims 1, 7, 21, 28, 34 and 40, and canceled claims 23, 24, 42 and 43. The amendment contains claim 11 as previously presented. However, claims 11, 12 and 15-20 were previously canceled by an amendment of 1/26/04.

Claims examined on the merits are 1-10, 13, 14, 21, 22, 25-41 and 44-46 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-10, 13, 14, 21, 22, 25-41 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The original specification fails to support coating a single cell or embryo with by micro-coating using capillary means and sucking the cell or embryo from a hydrocolloid solution into a capillary as now required in claims 1 and 28, and claims dependent thereon. The original disclosure contains no description of using a capillary as required by claim 1 when coating a single cell. The disclosure of using a 1.5 mm tube for sucking an embryo from a solution of

hydrocolloid in the specification (page 4, lines 1-2) is when coating an embryo and not a single cell. Additionally, disclosing the use of this 1.5 mm tube when coating an embryo does not support the broader concept of using any capillary as encompassed by claim 28 when coating an embryo.

The specification does not recite the terms "micro-coating" and "capillary means" recited in claims 1 and 28, and these terms provide a concept and scope of the invention different than originally disclosed.

Adequate support is not found in the specification for the ranges "1 to 5%" and "6 to 8%" that are recited in claims 1 and 28. These ranges are not recited in the specification, and support is not found for creating ranges having lower and upper limits as claimed.

In claims 21 and 40, there is not support for a capillary having an approximate or smaller diameter than the diameter of a cell and embryo being sucked into the capillary. The specification discloses only a diameter of 1.5 mm. Furthermore, if the tube diameter is smaller than the cell or embryo diameter, it is not seen how the cell or embryo can enter the tube.

Response to Arguments

In view of the evidence presented by applicants, it is granted that the 1.5 mm tube disclosed in the specification at page 4, lines 1-2, is a capillary tube. However, the tube is disclosed only when coating an embryo, and an embryo is not a single cell. Additionally,

the use of this single diameter tube, does not support the use of any diameter capillary as not encompassed by the claims.

In regard to the ranges, applicants urge that coating thickness can be found in the specification at page 16, lines 31 and 32, and in Figures 8 and 9, and using calculations achieved manually by ruler or by computer, thickness of coating as a percentage of cell diameter can be revealed. However, adequate support is not found in the section of the specification and figures referred to for ranges having upper and lower limits as claimed. There is no basis for the lower and upper limits being values that are boundary lines the invention must be practiced within. The ranges provide a concept and scope of the invention not originally disclosed. It is uncertain as to the kind of calculations used since the calculations have not been specifically described.

Claim Rejections - 35 USC § 112

Claims 1-10, 13, 14, 21, 22, 25-41 and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "micro-coating" and "capillary means" in claims 1 and 28 are uncertain as to meaning and scope. The terms are not recited and defined in the specification. The terms are relative and subjective, and their meaning can vary depending on individual interpretation.

In line 2 of claim 1, "micro-coating by formed capillary means" is confusing.

In the last line of claim 1, "of the hydrocolloid" is confusing and not needed since the penultimate line recites "when the hydrocolloid is".

In line 2 of claims 21 and 40, --- solution --- should be inserted after "hydrocolloid" to be clear.

Claims 21 and 40, in line 1, are confusing by not having antecedent basis for "cell or embryo". Claim 1 is coating only a single cell and claim 28 is coating only an embryo. Claims 21 and 40 are inconsistent with the claims on which they depend. Additionally, "cell or embryo" is inconsistent with line 3 of each claim requiring a cell.

Claims 21 and 40 are confusing and unclear by requiring a thin capillary having an approximate or smaller diameter than the diameter of the cell since a cell having a larger diameter than the capillary diameter cannot be sucked into the capillary. Furthermore, it is uncertain as to structure of a capillary that is "thin" since the specification discloses a tube that is round.

In line 11 of claim 28, "LMP" should be changed to --- low-methoxy pectin (LMP) --- to be consistent with dependent claim 31. Similarly, in the penultimate line of claim 1, --- (LMP) --- should be reinserted to be consistent with dependent claim 4.

In dependent claims 5 and 32, the abbreviations for "iota" and "kappa" should be replaced with --- iota --- and --- kappa --- to be consistent with independent claims 1 and 28.

In line 1 of dependent claim 34, there is not antecedent basis for "the cell" since independent claim 28 requires an embryo.

Response to Arguments

While the amendment has overcome some of the claim indefiniteness, indefiniteness still remains in the claims. Furthermore, in certain instances, an amendment has created additional indefiniteness.

Claim Rejections - 35 USC § 103

Claims 1-6, 8-10, 13, 14, 21, 22 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nussinovitch et al (6,068,867) in view of Soon-Shiong et al (5,762,959) and Dorian et al (5,693,514) and Togawa (5,348,883) for reasons in the previous office action 4/7/04 and for reasons herein.

The claims are drawn to coating a single cell by placing the cell in a hydrocolloid solution, removing the cell from the solution by sucking into a capillary, placing the cell in a cross-linking solution to provide the cell with a coating with a thickness of 1 to 5% of the cell diameter when the hydrocolloid is iota- or kappa-carrageenan or a thickness of 6 to 8% of the cell diameter when the hydrocolloid is low-methoxy pectin or alginate, and storing the cell in solution.

Nussinovitch et al disclose coating various materials such as bulbs, fungi, etc. (Col 3, lines 1-4) by placing material in a hydrocolloid solution such as an alginate solution, allowing excess

solution to drip from the material and immersing the material in a gel inducing agent such as chloride salt or calcium salt. For example, see col 1, line 42 to col 3, line 20, and Examples 1 and 2.

Soon-Shiong et al disclose microencapsulation of cells in alginate.

Dorian et al disclose using non-fibrogenic high mannuronate alginate to coat transplants such as pancreatic islets.

Togawa discloses using a capillary to transfer a cell (col 6, lines 19-35) and to remove liquid by sucking the liquid through a capillary (col 7, line 9) when carrying out a method of selecting cells.

It would have been obvious to apply the alginate coating procedure of Nussinovitch et al to a single cell in view of Soon-Shiong et al microencapsulating cells in alginate and Dorian et al coating islets with high mannuronate alginate, and since Nussinovitch et al disclose using the coating procedure to coat different materials including fungi. Using a capillary to remove the cell from the hydrocolloid solution by sucking the cell into the capillary would have been obvious in view of Togawa transferring a cell using a capillary and removing a solution by sucking through a capillary. Storing the cell in solution would have been obvious since Soon-Shiong et al and Dorian et al may store cells in solution. No unexpected result has been established by storing in solution as compared to drying.

Response to Arguments

Applicants urge that coating a single cell with a micro-coating by capillary means by sucking a cell into a capillary is not suggested by

Nussinovitch et al, Soon-Shiong et al and Dorian et al. However, when using a capillary to transfer a single cell as suggested by Togawa, it would have been expected that a single cell can be coated. While Togawa use an adhesive on a capillary, it would have been expected that the adhesive can be omitted in view of Togawa sucking a solution through the capillary. The capillary in the present invention is functioning as a transfer tool to move the single cell from one solution to another, which is the same type capillary function disclosed by Togawa. There is inadequate evidence that the coating thickness of the present claims is different than the coating thickness of Nussinovitch et al.

Applicants urge that there is no motivation to combine Togawa with the other references. However, Togawa suggest the function of a capillary to transfer a cell, and this would have been motivation to use a capillary when coating a cell. Additionally, it would have been obvious to coat a single cell for same reason that Soon-Shiong et al and Dorian et al coat cells. No unexpected result is seen in coating a single cell as compared to coating cells as disclosed by Soon-Shiong et al and Dorian et al. Moreover, the working embodiment demonstrated in the specification is coating an embryo, which is normally multiple cells rather than a single cell.

Claim Rejections - 35 USC § 103

Claim 7, 28-41 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-6, 8-10,

13, 14, 21, 22 and 25-27 above, and further in view of Jorgensen et al ('838) for reasons in the previous office action.

The claims require coating an embryo or an Xenopus laevis egg or embryos.

Jorgensen et al disclose protecting an egg by encapsulating the egg in a gel material (col 1, lines 54-60).

When applying the coating procedure of Nussinovitch et al to a cell as set forth above, it would have been obvious to apply the coating to a Xenopus laevis egg or embryo to obtain the protective function of the coating as suggested by Jorgensen et al.

Response to Arguments

Contrary to applicants' argument, Jorgensen et al is not necessarily forming a gel matrix containing the egg since when adding the carrageenan solution containing the egg dropwise, the drops may contain only one egg depending on the size of the drops. In any event, when using a capillary for transfer of the egg it would have been expected that a single egg can be encapsulated.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In

the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
1/10/05